SEXUALLY TRANSMITTED DISEASE TESTING IN CALIFORNIA

1999 Annual Clinical Laboratory Survey Summary

Introduction

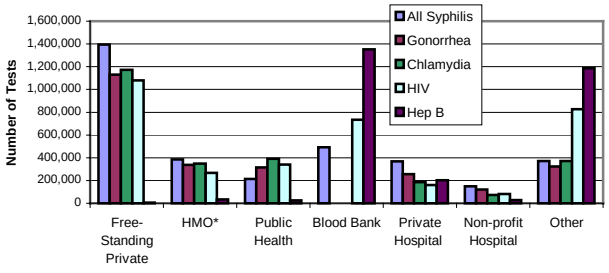
Timely, accurate, and complete laboratory reporting is essential to health department efforts to effectively identify public health problems and to design cost-effective interventions. Reports are used to intervene with individual patients, and to defuse potential outbreak situations. Although California regulations require both health care providers and laboratories to report selected sexually transmitted diseases (STDs) to the health department, the majority of disease reports are initially received from laboratories.

Laboratories are legally mandated to report findings indicative of syphilis, gonorrhea, chlamydia, hepatitis B and chancroid to local health departments for case follow-up activity and epidemiologic analysis. Currently, acquired immune deficiency syndrome (AIDS) is a reportable condition, non name-based human immunodeficiency virus (HIV) reporting will become mandatory in California on July 1, 2002.

Since 1996, the California Department of Health Services (DHS), Division of Communicable Disease Control, Sexually Transmitted Diseases (STD) Control Branch has surveyed clinical laboratories throughout California that perform testing for syphilis, gonorrhea, or chlamydia.

The Annual Clinical Laboratory Survey assists disease control efforts by identifying the number and types of laboratories performing STD testing, trends in the types of test technologies used, including the implementation of test technologies having the highest sensitivity and specificity, and the number of tests performed by each method. The survey also provides information regarding current morbidity trends. This report summarizes information from the 1999 Annual Laboratory Survey. These data are presented with additional surveillance and trend information from the annual California STD Report.

Figure 1. Number of STD Tests Performed by Type of Laboratory, 1999



Source: California DHS STD Control Branch

Overview

The 1999 Annual Clinical Laboratory Survey was sent to 617 laboratories that potentially conducted testing for reportable diseases. Of these, 571 labs responded to the survey, resulting in a response rate of 92 percent (see technical note for further explanation - page 4).

Figure 2. Number and Percent of Syphilis, Gonorrhea, Chlamydia and HIV* Tests Performed by Laboratory Type

	1996 N=11,258,938	1997 N=12,009,381	1999 N=11,883,545
Type of Laboratory	%	%	%
Free-Standing Private	38.2%	30.4%	40.2%
HMO*	10.0%	10.5%	11.2%
Public Health	9.9%	9.4%	10.6%
Blood Bank	11.2%	12.3%	10.3%
Private Hospital	3.7%	8.1%	8.1%
Non-profit Hospital	9.0%	9.0%	3.6%
VA**/Military Hospital	0.4%	1.1%	1.3%
University/Teaching Hospital	n/a	n/a	1.3%
Physicians/Group Practice	6.8%	2.0%	1.1%
Student Health Services	0.6%	0.4%	0.5%
Community Clinic Lab	0.7%	0.4%	0.4%
Correctional Facility	0.7%	0.8%	0.3%
Other	8.9%	15.5%	11.0%

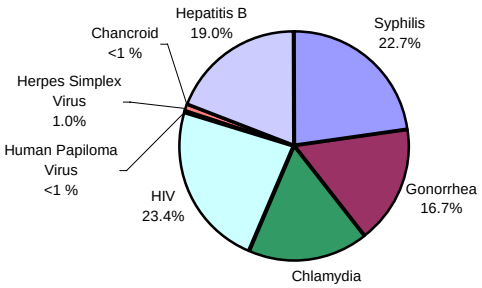
*health maintenance organization **Veterans Administration

Source: California DHS STD Control Branch

Private sector (non-public health) laboratories performed the majority of all STD tests reported in 1999, conducting 93.6% of syphilis, 87.3% of gonorrhea, 84.5% of chlamydia, and 90.2% of HIV tests. The largest proportion of tests was conducted by free-standing private facilities, performing 40.2% of all syphilis, gonorrhea, chlamydia, and HIV tests (Figure1, Figure 2).

Of all laboratory tests performed to detect STDs, the largest percentage was for HIV (23.4%), followed by syphilis (22.7%) and hepatitis B (19.1%). (Figure 3).

Figure 3. STD Tests Performed, 1999



Source: California DHS STD Control Branch

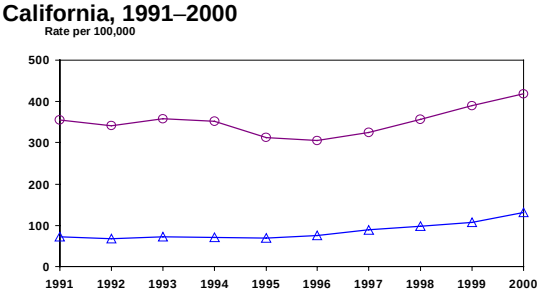
Reportable STDs

For each of the reportable diseases, information from California's case-based surveillance system is included to provide a context for interpreting laboratory information.

Chlamydia

- *Chlamydia trachomatis* remains the most commonly reported infectious disease in both California and the United States.
- In 1999, the rate of chlamydia among females was 390.3 cases per 100,000, and 106.5 per 100,000 among males, an increase of 9.0% from 1991 rates. (Figure 4).

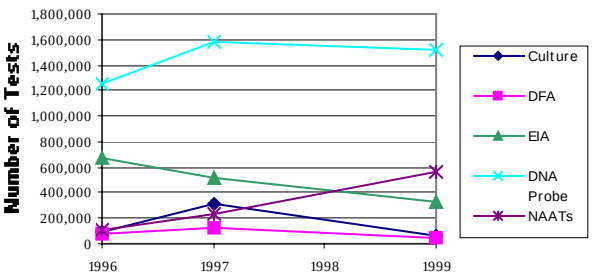
Figure 4. Chlamydia, Rates by Gender, California, 1991–2000



Source: California DHS STD Control Branch

- Based on lab survey data, a total of 2,542,546 chlamydia tests were performed in 1999, representing a decrease of 9.2% from 1997 (Appendix 1).
- Excluding serologies, which are not recommended for patient clinical management, 3.7% of all reported lab tests for chlamydia were positive.
- Nucleic acid amplification testing (NAAT) in the form of ligase chain reaction (LCR), polymerase chain reaction (PCR), and transcription mediated amplification (TMA) increased from 4.9% of tests in 1996 to 22.2% of tests in 1999. (Figure 5).

Figure 5. Chlamydia Test Numbers by Type of Test



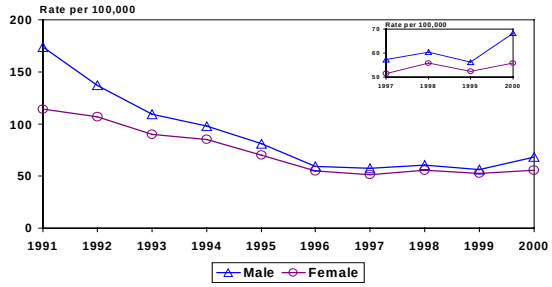
Source: California DHS STD Control Branch

- In 1999, the most commonly used chlamydia test was the DNA probe (60.0%), followed by NAAT (22.2%), and enzyme immuno assay (EIA) (12.9%).
- False positive STD test results cause unnecessary health care and emotional costs for patients and their partners. Although the Centers for Disease Control and Prevention (CDC) strongly recommends using verification assays to increase the specificity of DNA probes and EIA testing, only about half (46.9%) of laboratories reported performing verification assays in 1999.
- The National Chlamydia Laboratory Committee recommends performing negative gray zone supplemental testing to enhance the sensitivity of non-amplification test technologies; 49.3% of laboratories reported following this recommendation in 1999.

Gonorrhea

- Gonorrhea cases declined from 144.3 per 100,000 population in 1991 to 54.8 per 100,000 in 1999. In 2000, gonorrhea rates increased slightly to 62.7 per 100,000 (Figure 6). Rates increased in both males and females and are continued to increase in 2001.
- Labs surveyed performed a total of 2,481,180 gonorrhea tests, an increase of 6.0% from 1997 (Appendix 2). Overall, 1.0% of all reported lab tests for gonorrhea were positive.

Figure 6. Gonorrhea, Rates by Gender, California, 1991–2000

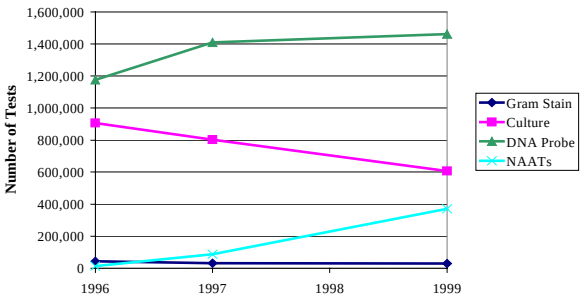


Source: California DHS STD Control Branch

- There was an increase of 3.7% in DNA probe testing from 1997, as well as a 328.9% increase in NAAT (LCR and PCR) from 86,651 in 1997 to 371,715 in 1999 (Figure 7).
- DNA probe testing was widely used, accounting for 58.9% of all tests.

- Use of culture is decreasing. Because culture specimens are necessary to test for antibiotic susceptibility, the decreasing number of cultures collected may impact the ability to monitor antibiotic resistance.
- Of laboratories that reported culture testing for gonorrhea, 46.3% reported beta-lactamase testing of isolates. Based on findings from the CDC Gonococcal Isolate Surveillance Project, which evaluates the antimicrobial resistance of Neisseria gonorrhoeae, penicillinase-producing N. gonorrhoeae is endemic at such levels that penicillin is no longer included as recommended treatment for gonorrhea. Therefore, monitoring beta-lactamase levels is of little clinical value and is unnecessary, according to the CDC.

Figure 7. Gonorrhea Test Numbers by Type of Test

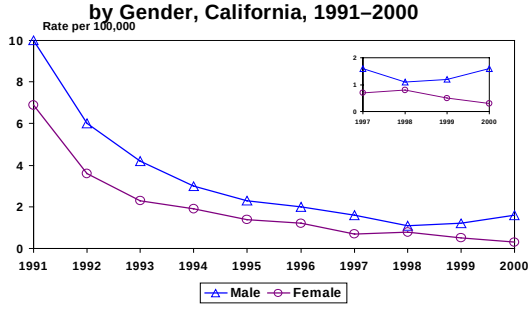


Source: California DHS STD Control Branch

Syphilis

- In 1999, 0.8 cases of primary and secondary syphilis per 100,000 population were reported in California. This represents a substantial decline from 1991, when the rate was 8.5 cases per 100,000.
- In 2000 and 2001, however, primary and secondary syphilis rates have been increasing, particularly among men who have sex with men (MSM) (Figure 8).
- Labs in California reported 3,373,531 tests for syphilis in 1999.
- 2.0% of laboratory-reported non-treponemal tests were positive, whereas 11.5% of all treponemal tests were positive.
- Non-treponemal testing comprised 85.9% of all syphilis tests performed in 1999. Rapid plasma reagins (RPR)s accounted for 96.0% of all non-treponemal tests performed. Venereal disease research laboratory (VDRL)s accounted for 4.0%.
- Microhemagglutination Assay for Antibodies to Treponema Pallidum (MHA-TP) accounted for 72.9% of all treponemal tests. Fluorescent Treponemal Antibody Absorption (FTA-ABS) accounted for 16.7% of the tests.

Figure 8. Primary and Secondary Syphilis, Rates by Gender, California, 1991–2000



Source: California DHS STD Control Branch

Hepatitis B

- A total of 2,835,875 hepatitis B surface antigen tests were reported by California labs in 1999, the majority of which (99.1%) were performed by private labs.
- In 1999, 2.2% of reported hepatitis B antigen tests were positive.

Chancroid

- Chancroid is rare in the United States; only 143 cases were reported in the country in 1999.
- Only 6 cases of chancroid were reported in California in 1999.
- Laboratories reported only 291 tests for chancroid in 1999, all of which were cultures. None of the tests were positive.

Non-reportable STDs: Testing for HIV, HPV, and HSV

Human Immunodeficiency Virus (HIV)

- A total of 3,487,032 HIV tests were performed; excluding viral load tests, 3.4% (55,467) were positive.
- The majority of the tests performed were serum EIA (67.3%), 10.1% were viral load tests, confirmatory testing (Western blot and immunofluorescent assay (IFA)) accounted for a combined total of 1.1% of all tests.
- Of the 35,838 Western blots performed, 70.8% were positive, while 71.8% of 2,288 IFA tests were positive.

Human Papillomavirus (HPV)

- Only seven laboratories in California offered HPV testing in 1999, performing a total of 19,924 tests.
- HPV testing is not currently recommended for patient clinical management.
- Of HPV tests, 4,078 (20.5%) were positive.

Herpes Simplex Virus (HSV)

- A total of 168,968 tests were performed for HSV-2.
- The most widely used test was culture, accounting for 74.7% of all tests performed.
- IFA accounted for 6.06% of tests, and EIA for another 2.67%.
- Of all reported lab tests, 21.7% were positive.

Summary

Survey data for 1999 documented more than 14.8 million STD tests.

Amplified testing for gonorrhea and chlamydia has increased, currently accounting for 15.0% and 22.2% of gonorrhea and chlamydia testing, respectively.

Gonorrhea culture testing has decreased, which may affect future antibiotic resistance testing.

Additional resources

Information on disease trends, recent reports and treatment guidelines can be found at the STD Control website:
http://www.dhs.ca.gov/ps/dcdc/STD/stdindex.htm

Information about infectious disease reporting, including a list of reportable diseases and reporting laws, can be found at the Disease Investigations and Surveillance Branch website:
http://www.dhs.ca.gov/ps/dcdc/disb/disbindex.htm

Technical notes:

The annual survey was not conducted in 1998. In June, 2000, surveys were mailed to all laboratories that had indicated on the 1997 survey that they performed STD testing, or that had been licensed after 1998.

Los Angeles County Department of Health Services STD Control Program conducts a laboratory survey for laboratories located in Los Angeles County. All other laboratories in California are surveyed by the California Department of Health Services STD Control Branch.

Of 879 labs that received surveys, 262 indicated that they were draw stations only, had closed, or did not perform STD testing.

Of the remaining 617 laboratories, 14 did not return the survey at all, and an additional 32 did not provide sufficient information to include in the analysis.

There were 571 laboratories that returned surveys with complete information.

Appendix 1: CHLAMYDIA TESTING IN CALIFORNIA, 1996-1999

STD & Type of Test	Test Characteristics	Testing Year (# of responding laboratories)								
		1996			1997			1999		
		PUBLIC (46)	PRIVATE (705)	TOTAL (751)	PUBLIC (44)	PRIVATE (637)	TOTAL (681)	PUBLIC (41)	PRIVATE (530)	TOTAL (571)
CHLAMYDIA Culture	# of tests	6,771	90,023	96,794	4,747	309,061	313,808	2,749	52,685	55,434
	# positive tests	478	2,428	2,906	318	2,096	2,414	82	1,105	1,187
	% positive*	7.1	2.9	3.2	6.7	3.6	3.8	3.0	2.1	2.1
CHLAMYDIA DFA	# of tests	8,305	69,548	77,853	5,145	116,481	121,626	3,259	46,844	50,103
	# positive tests	1,157	2,325	3,482	428	2,509	2,937	233	1,238	1,471
	% positive*	14.0	3.5	4.7	8.3	3.0	3.3	7.1	2.6	2.9
CHLAMYDIA EIA	# of tests	112,985	553,685	666,670	78,478	437,493	515,971	13,701	314,566	328,267
	# positive tests	6,020	18,726	24,746	3,879	16,794	20,673	1,193	10,529	11,722
	% positive*	5.4	3.4	3.7	4.9	4.4	4.5	8.7	3.3	3.6
CHLAMYDIA DNA	# of tests	80,438	1,167,789	1,248,227	77,669	1,509,960	1,587,629	51,362	1,473,663	1,525,025
	# positive tests	1,827	34,395	36,222	2,671	31,521	34,192	2,003	48,279	50,282
	% positive*	3.4	3.3	3.3	3.4	3.5	3.5	3.9	3.3	3.3
CHLAMYDIA LCR	# of tests	18,608	12,896	31,504	82,460	46,878	129,338	212,341	212,964	425,305
	# positive tests	931	466	1,397	5,285	5,636	10,921	12,020	9,223	21,243
	% positive*	5.2	3.6	4.5	6.4	5.9	6.2	5.7	4.3	5.0
CHLAMYDIA PCR	# of tests	68,041	8,068	76,109	91,493	10,657	102,150	96,179	31,812	127,991
	# positive tests	5,305	305	5,610	6,087	121	6,208	6,543	925	7,468
	% positive*	7.8	3.8	7.4	6.7	2.1	6.4	6.8	2.9	5.8
CHLAMYDIA TMA	# of tests	-	-	-	2,202	-	2,202	11,217	-	11,217
	# positive tests	-	-	-	118	-	118	519	-	519
	% positive*		-		5.4		5.4	4.6	N/A	4.6
CHLAMYDIA SEROLOGY**	# of tests	-	-	-	-	-	-	-	14,498	14,498
	# positive tests	-	-	-	-	-	-	-	1,028	1,028
	% positive*							N/A	7.1	7.1
CHLAMYDIA OTHER	# of tests	-	-	-	-	-	-	1,132	3,574	4,706
	# positive tests	-	-	-	-	-	-	59	260	319
	% positive*							5.2	7.3	6.8
CHLAMYDIA TOTAL	# of tests	295,148	1,905,793	2,200,941	342,194	2,435,016	2,777,210	390,808	2,132,534	2,542,546
	# positive tests	15,718	58,753	74,471	18,786	58,820	77,606	22,593	71,299	95,239
	% positive*	5.9	3.3	3.6	5.6	3.8	4.1	5.8	3.3	3.7

*Percent positive was calculated using only those surveys that provided both the number processed and the number positive ** Not a recommended test

Appendix 2: GONORRHEA AND SYPHILIS TESTING IN CALIFORNIA, 1996-1999

STD & Type of Test	Test Characteristics	Testing Year (# of responding laboratories)								
		1996			1997			1999		
		PUBLIC (46)	PRIVATE (705)	TOTAL (751)	PUBLIC (44)	PRIVATE (637)	TOTAL (681)	PUBLIC (41)	PRIVATE (530)	TOTAL (571)
SYPHILIS RPR & VDRL	# of tests	217,215	3,742,214	3,959,429	200,644	2,880,811	3,081,455	198,546	2,700,498	2,899,044
	# positive tests	16,811	66,738	83,549	17,090	89,091	106,181	9,217	45,669	54,886
	% positive*	8.4	2.4	2.8	8.6	3.2	3.6	4.64%	1.69%	1.89%
GONORRHEA Gram Stains	# of tests	9,817	34,040	43,857	7,656	23,461	31,117	3,380	26,828	30,208
	# positive tests	1,372	1,528	2,900	1,238	586	1,824	692	464	1,156
	% positive*	14.1	4.7	6.9	16.5	2.7	1.3	20.47%	1.73%	3.83%
GONORRHEA Culture	# of tests	185,507	720,840	906,347	158,354	645,056	803,410	52,485	554,260	606,745
	# positive tests	5,993	6,104	12,097	4,603	5,721	10,324	1,674	3,874	5,548
	% positive*	3.3	0.9	1.4	2.9	0.9	1.3	3.19%	0.70%	0.91%
GONORRHEA DNA Probe	# of tests	73,626	1,104,238	1,177,864	75,523	1,334,210	1,409,733	60,183	1,402,405	1,462,588
	# positive tests	540	9,115	9,655	812	7,103	7,915	710	11,702	12,412
	% positive*	1.1	1.0	1.0	1.2	0.9	0.9	1.18%	0.83%	0.85%
GONORRHEA LCR/TMA	# of tests	4,735	7,959	12,694	52,685	33,966	86,651	196,665	175,050	371,715
	# positive tests	80	304	384	870	228	1,098	4,023	1,480	5,503
	% positive*	1.9	3.8	3.2	1.7	0.7	1.3	2.05%	0.85%	1.48%
GONORRHEA OTHER	# of tests	-	-	-	-	-	-	1,732	8,192	9,924
	# positive tests	-	-	-	-	-	-	12	85	97
	% positive*	-	-	-	-	-	-	0.69%	1.04%	0.98%
GONORRHEA TOTAL	# of tests	273,699	1,870,545	2,144,244	294,411	2,037,932	2,332,343	314,445	2,166,735	2,481,180
	# positive tests	7,998	17,075	25,073	7,667	13,640	21,307	7,111	17,605	24,716
	% positive*	3.2	1.0	1.3	2.7	0.9	1.2	2.26%	0.81%	1.00%

*Percent positive was calculated using only those surveys that provided both the number processed and the number positive